UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

REGENTS OF THE UNIVERSITY OF MINNESOTA,

Plaintiff,

v.

AGA MEDICAL CORPORATION,

Defendant.

Case No. 07-CV-4732 (PJS/LIB)

ORDER

Kevin D. Conneely, David D. Axtell, Ruth Rivard, and Benjamin P. Freedland, LEONARD, STREET AND DEINARD, PA; Tracy M. Smith, THE UNIVERSITY OF MINNESOTA, for plaintiff.

J. Derek Vandenburgh, Alan G. Carlson, R.J. Zayed, and Tara C. Norgard, CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A., for defendant.

Defendant AGA Medical Corporation ("AGA") moves for summary judgment that the claims of U.S. Patent No. 6,077,281 (the '281 patent) asserted by plaintiff Regents of the University of Minnesota ("the University") are invalid. According to AGA, the claims are invalid for three reasons: (1) they are anticipated; (2) they are indefinite; and (3) they are not enabled. For its part, the University moves to exclude certain evidence that relates to AGA's enablement argument.

For the reasons that follow, the Court grants summary judgment of invalidity to AGA on the basis of both anticipation and indefiniteness. But because the Court finds that AGA's evidence with respect to enablement is untimely, the Court excludes the evidence and rejects AGA's enablement argument.

The Court's finding of invalidity means that the University cannot recover against AGA based on the '281 patent. And the University cannot recover against AGA based on the second patent at issue in this case — U.S. Patent No. 6,077,291 (the '291 patent) — because, in an earlier order, the Court granted summary judgment of noninfringement to AGA. Order on Mot. for SJ of Noninfringement ("Second SJ Order") at 12-13 [Docket No. 231].[1] Thus, the only issues remaining in this case relate to AGA's declaratory-judgment counterclaims. Because those counterclaims all plead, in various ways, that the patents asserted by the University are invalid, not infringed, or unenforceable, the Court exercises its discretion to dismiss AGA's remaining counterclaims as moot, and the Court directs that judgment be entered dismissing the University's complaint.

I. BACKGROUND

The University sued AGA for allegedly infringing the '281 and '291 patents. Both patents cover medical devices for repairing heart defects. The University owns the patents, which are part of a family of four patents covering inventions made by Gladwin S. Das. The University prosecuted all four patents as Das's assignee.

The Das patents descend from an application filed in 1992. The University abandoned the original application, but subsequent divisional applications resulted in four patents: U.S. Patent No. 5,334,217, issued in April 1994; U.S. Patent No. 5,578,045, issued in November

[1]In an even earlier order, the Court granted in part and denied in part AGA's motion for summary judgment that the '291 patent expired. The Court held that the '291 patent expired on June 20, 2004, and cannot be asserted after that date. Order Apr. 18, 2008 [Docket No. 34].

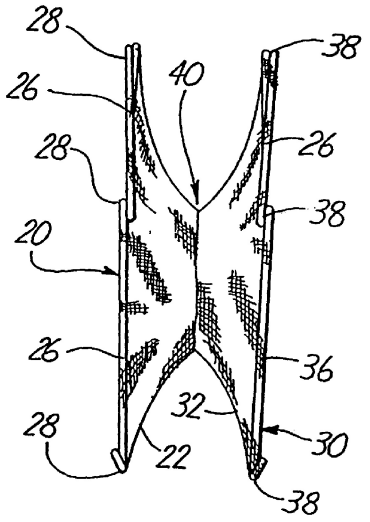
1996; and the '281 and '291 patents, both of which were issued on June 20, 2000. These four patents include different claims but generally share the same specification.[2]

Roughly speaking, all of the Das patents cover a closure device (commonly called an "occluder") for repairing a hole between two chambers of a human heart. The occluder is delivered through a catheter that is threaded through a vein or artery until the catheter's far end reaches the hole to be closed.

The occluder features two disks that are joined at the center. The disks, which are springy, are folded up and pushed through a catheter. The far end of the catheter is placed through the hole in the heart. The occluder is then pushed forward through the catheter until the first half of the occluder (i.e., the first disk) comes out of the catheter on the far side of the hole and springs back into its disk-like shape. The catheter is then pulled back to the near side of the hole with the second half of the occluder (i.e., the second disk) still inside the catheter. The occluder is pushed forward again until the second disk springs out, this time on the near side of the hole. The area where the two disks are joined blocks the hole, and the disks stay in position for two reasons: (1) they are bigger than the hole, and (2) they are springy. The central portion of the disk soon becomes solid in one of a number of ways, and at that point, the hole is closed.

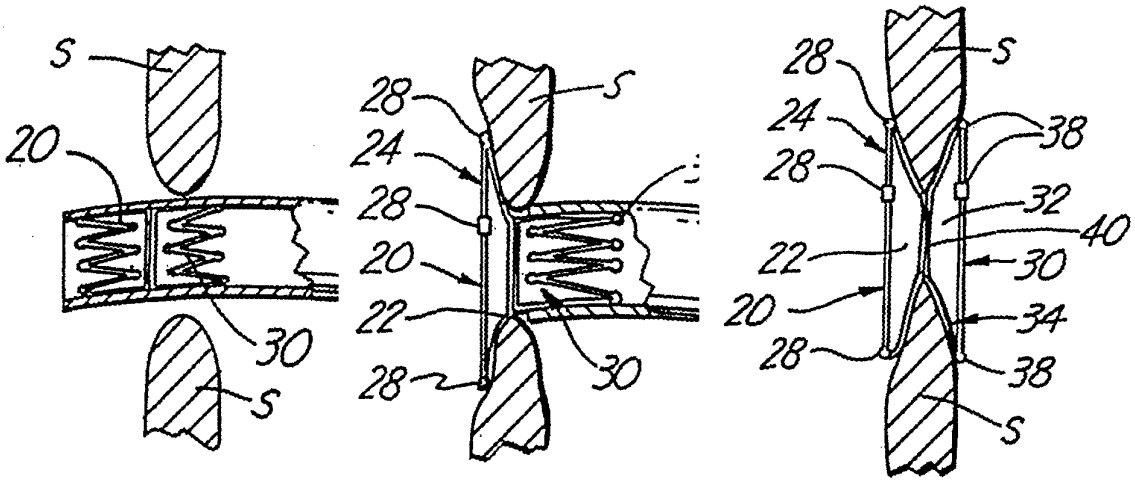
The following drawing from the '281 patent depicts a side view of an embodiment of the occluder with both disks in their fully expanded shape:

[2]The abstract of U.S. Patent No. 5,578,045 differs from the abstract of the other patents. The claims of patent 5,578,045 cover a delivery system for implanting a device for repairing heart defects, not the device itself.



'281 Pat. Fig. 3.

The following series of drawings from the '281 patent show the same embodiment of the occluder as it is being deployed to close a hole in a patient's heart:



'281 Pat. Figs. 8-10 (cropped and rearranged).

II. DISCUSSION

A. Standard of Review

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute over a fact is "material" only if its resolution might affect the outcome of the lawsuit under the substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute over a fact is "genuine" only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255.

B. Anticipation

A patent claim is invalid as anticipated under 35 U.S.C. § 102 if a single prior-art reference discloses, expressly or inherently, each limitation of the claim. *See, e.g.*, *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005). Anticipation can be thought of as a kind of retrospective infringement, because "that which would literally infringe if later anticipates if earlier." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001). Anticipation is a question of fact, and it must be established by clear and convincing evidence. *See id.* at 1374; *see also Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002) ("What a prior art reference discloses in an anticipation analysis is a factual determination . . . .").

According to AGA, two different devices described in two references each meet all of the limitations of claims 1, 4, and 5 of the '281 patent (the only asserted claims): (1) an occluder covered by U.S. Patent No. 3,874,388 to King; and (2) a "clamshell" occluder described in an

article from 1989 by James E. Lock et al. titled *Transcatheter Closure of Arterial Septal Defects: Experimental Studies,* 79 Circulation 1091 (1989) ("Lock article").[3] The Court will refer to these devices, respectively, as the "King device" and the "Lock device."[4]

The Court first sets out the asserted claims of the '281 patent as construed by the Court, then discusses the King and Lock devices in turn.

1. Asserted Claims of the '281 Patent

Claim 1 of the '281 patent claims:

> A septal defect closure device comprising a first member and a second member
>
> each comprising a self-expanding structure
>
> exhibiting a spring-like behavioural component for moving the member between a compressed orientation for passage through a medical instrument having an inner diameter and an expanded orientation having an enlarged diameter
>
> for tautly holding at least a portion of the closure device against a septum,
>
> the enlarged diameter of the member being greater than the inner diameter of the medical instrument;
>
> each of the first and second members also including a central portion,
>
> at least a substantial portion of the central portion of the first member being in communication with at least a substantial portion of the central portion of the second member.

[3]The Lock article is Exhibit 20 to the Vandenburgh Decl. [Docket No. 245]. The Lock article is also available online at http://circ.ahajournals.org/content/79/5/1091.full.pdf.

[4]The Lock article describes the use of other occluders besides the clamshell device. AGA does not contend that the other occluders anticipate the claims of the '281 patent.

‘281 Pat. col. 18:11-24 (amended to reflect a certificate of correction dated Dec. 24, 2002; line breaks added for clarity).

Roughly speaking, this claim is drawn to a two-part occluder. The two parts (“members”) connect in some way (i.e., “communicate[]”) at the center, can be folded up (“compressed”) for delivery, and will expand and become taut upon deployment. More specifically, the Court has construed the disputed language in this claim as follows:

> [T]he term “a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation . . . and an expanded orientation” . . . [is] a means-plus-function limitation subject to 35 U.S.C. § 112, ¶ 6. The claimed function and the structure that corresponds to this function are as follows:
>
> > The claimed function is moving the member from a compressed orientation to an expanded orientation. The structure that performs this function must be either: (1) a flexible, elastically deformable frame carried around the periphery of the member; or (2) a frameless membrane made of a thin piece of a superelastic material.

Markman Order at 21 [Docket No. 142].

> The term “tautly holding” derives from the phrase “to hold tautly.” “To hold something tautly against a septum” means both (1) to hold that thing itself taut, like a drum head or the surface of an inflated balloon, and (2) to hold that thing tightly against a septum.

Second SJ Order at 12-13.

> A portion of a first member is “in communication with” a portion of a second member if those two portions are arranged in such a way that movement of one portion is transmitted to the other portion.

Id. at 5.

Claim 4 adds a limitation directed to the relationship of the two members and provides that:

> the first member in its compressed orientation extends primarily distally from the second member and
>
> the second member in its compressed orientation extends primarily proximally from the first member,
>
> each member in its expanded orientation extending primarily radially outward from its central portion.

'281 Pat. col. 18:31-36 (line breaks added for clarity).

Finally, Claim 5 adds a limitation requiring that "each of the first and second members comprises a flexible fabric disk." *Id.* col. 18:37-38.

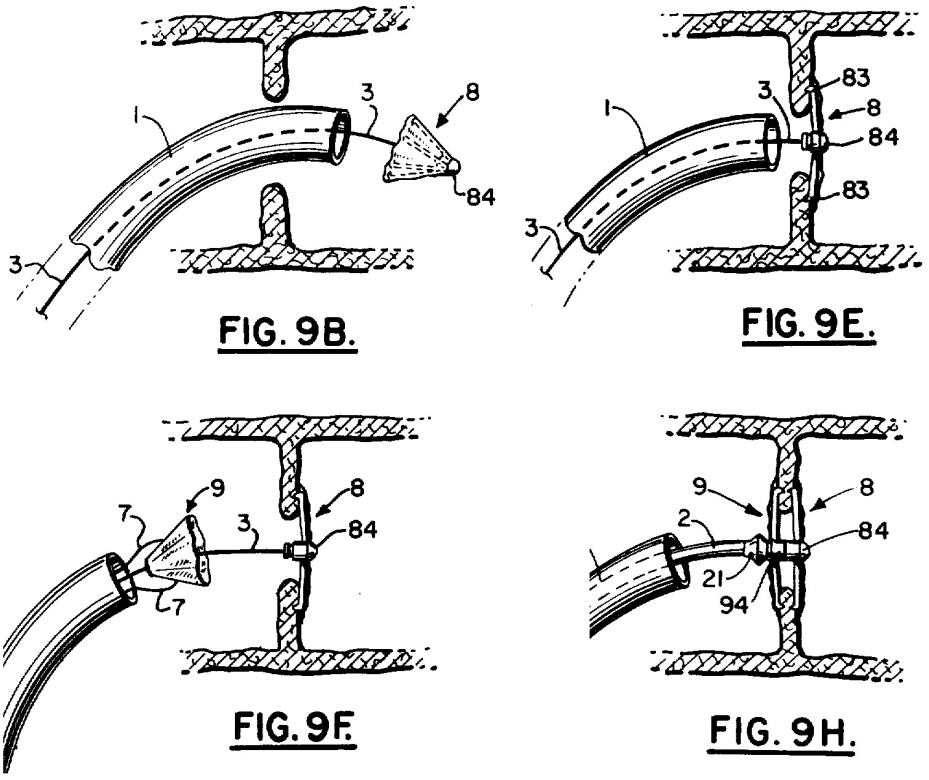
2. The King Device

The King device is a two-part occluder in which each part is shaped like an umbrella.[5] The umbrellas are delivered one at a time. That is, first one umbrella is delivered through a catheter to the far side of a defect, is opened (or opens automatically), and is seated around the defect by means of barbs at the ends of the umbrella's struts.[6] Then a second umbrella is delivered to the near side of a defect, is opened (or opens automatically), and is pushed forward

[5]The King patent also discloses a single-umbrella device for use in closing ventricular septal defects. *See* U.S. Pat. No. 3,874,388 col. 10:28 to col. 11:29. The single-umbrella device is irrelevant to this case because it does not have two "members," and the Court therefore disregards it.

[6]U.S. Pat. No. 3,874,388 col. 9:30-45 ("[T]he distal hub 84 carrying the collapsed left umbrella 8 is advanced . . . into the left atrium (Fig. 9B). Once the left umbrella 8 is pushed beyond the tip of the outer, thin wall catheter 1, the umbrella 8 is initially unfolded . . . . The outer catheter 1 is then pulled back into the right atri[um] and the umbrella 8 pulled snugly against the left atrial septum, with the distal barbs 83 being anchored against the septum (Fig. 9E).")

until the two umbrellas lock together at the center by means of a locking hub.[7] The following four illustrations from the King patent show the first umbrella being opened (Fig. 9B); the first umbrella in place (Fig. 9E); the second umbrella being opened (Fig. 9F); and the first and second umbrellas both in place (Fig. 9H):



U.S. Pat No. 3,874,388 Figs. 9B, 9E, 9F & 9H (cropped and rearranged).

[7]U.S. Pat. No. 3,874,388 col. 9:46 to col. 10:1 ("Once the left umbrella 8 is firmly fixed, the inner catheter 2 is withdrawn and removed and the right umbrella 9 slid into the obturator wire 3 and loaded into the outer catheter 1 . . . . The collapsed right umbrella 9 is then pushed through and out the outer catheter 1 . . . . [T]he right umbrella 9 is opened (Fig. 9G) and pushed snugly against the inter-atrial septum by means of inner catheter 2. . . . The inner catheter 2 is pushed further forward, forcing the sliding sleeve 94 of the right umbrella 9 to slide onto the left umbrella hub 84, locking the two together (Fig. 9H).")

It is apparent — and the University does not dispute — that the King device pictured in these illustrations meets some of the limitations of the asserted claims of the '281 patent. Specifically, the King device has first and second "members" (the umbrellas); the members have a "compressed orientation" that fits within a catheter and an "expanded orientation having an enlarged diameter"; the umbrellas include a "flexible fabric disk" (as called for by claim 5); and a portion of the opened umbrellas is held "tautly" against the septum. *See* O'Laughlin Decl. Ex. 1 ("O'Laughlin Rept.") at 28-32 [Docket No. 256] (opining that the King device does not anticipate and not discussing any of these limitations).

But the University's expert witness, Dr. Martin O'Laughlin, denies that the King device meets other limitations. First, O'Laughlin says that the King device does not meet the limitation calling for "a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation . . . and an expanded orientation." *See* O'Laughlin Rept. at 28. As the Court has construed it, this limitation requires a structure that moves a member from a compressed orientation to an expanded orientation, and that structure "must be either: (1) a flexible, elastically deformable frame carried around the periphery of the member; or (2) a frameless membrane made of a thin piece of a superelastic material." *Markman* Order at 21. O'Laughlin asserts — correctly — that the King device does not include a structure of either type. O'Laughlin Rept. at 28.

AGA agrees that the King device does not include a peripheral frame or a frameless, superelastic membrane. But AGA's expert witness, Dr. Charles E. Mullins, argues that when the King device is made with springy radial arms that automatically open the umbrella (as opposed to non-springy arms, which can also be used), those springy radial arms are equivalent to a

peripheral frame. *See* Mullins Decl. Ex. 1 ("Mullins Rept.") at 24 [Docket No. 244] ("[T]he umbrella leg frame structure disclosed in King is an equivalent structure to the peripheral leg frame structure disclosed in the '281 patent for the stated function.").[8]

In general, a means-plus-function limitation includes not just the specific structures linked to the function in the patent (in this case, the peripheral frame and a frameless, superelastic membrane). Rather, a means-plus-function limitation includes those structures *and* their equivalents. 35 U.S.C. § 112, ¶ 6 ("An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure . . . in support thereof, and such claim shall be construed to cover the corresponding structure . . . described in the specification *and equivalents thereof*." (emphasis added)). The question, then, is whether a dispute of fact exists over whether springy radial umbrella arms are equivalent to a springy peripheral frame. The Court finds that no such dispute exists.

To decide whether two structures are equivalent for purposes of meeting a means-plus-function limitation, a factfinder must ask whether the structure proposed as an equivalent "results from an insubstantial change which adds nothing of significance to the structure, material, or acts disclosed in the patent specification." *Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1043 (Fed. Cir. 1993). In answering this question, the factfinder applies a truncated version of the so-called "function-way-result" test that applies in the doctrine-of-equivalents context. *See Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed. Cir. 1999) ("[T]he statutory

[8]The King patent clearly discloses the use of springy radial arms. *See* U.S. Pat. No. 3,874,388 col. 8:48-53 ("[A]s generally illustrated in FIG. 12B, the struts 91 could be made of resilient, flexible material so that the umbrella will inherently or automatically open once it emerges from the outer catheter (note the movement of the phantom lined strut).").

equivalence analysis [under § 112, ¶ 6], while rooted in similar concepts of insubstantial differences as its doctrine of equivalents counterpart, is narrower.").

Specifically, because a structure cannot satisfy a means-plus-function limitation unless it literally performs the claimed function, the "function" prong of the function-way-result test will always, of necessity, be met when considering equivalence under § 112, ¶ 6. Thus, a factfinder need only determine whether an ostensibly equivalent structure in an accused device performs the claimed function in the same "way," and with the same "result," as the specific structures linked to the function in the patent.[9]

There can be no dispute that the springy radial umbrella arms of the King device and the peripheral radial frame in the '281 patent perform the same function and reach the same result. Both structures cause an occluding disk to move from a compressed to an expanded orientation (the function), and both have the same result (an expanded disk). The only question, then, is whether they operate in the same way. Based on the parties' competing expert testimony, a reasonable jury would have to find that they do.

In support of AGA, Mullins says:

> [T]he legs between the resilient loops of the '281 patent operate in the same way as the legs in the King patent because they are folded

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[9] *Odetics,* 185 F.3d at 1267 ("[U]nder § 112, ¶ 6 equivalence, functional *identity* is required; thus the equivalence (indeed, identity) of the 'function' of the assertedly substitute structure, material, or acts must be first established in order to reach the statutory equivalence analysis. The content of the test for insubstantial differences under § 112, ¶ 6 thus reduces to 'way' and 'result.'" (emphasis in original; citations omitted)); *see also JVW Enters. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1333 (Fed. Cir. 2005) (citing *Odetics* and holding: "For the relevant structure in the accused device to be equivalent to the structure in the written description, differences between the two must be insubstantial. For example, the structure in the accused device must perform the claimed function in substantially the same way to achieve substantially the same result as the structure in the written description." (citations omitted)).

> to allow the frame to be made small enough to fit within the catheter and they then unfold upon exiting the catheter to permit the frame member to assume an expanded orientation with an enlarged diameter.

Mullins Rept. at 24. In other words, according to Mullins, the "way" the radial umbrella arms of the King device operate is by folding and unfolding, and the legs of the peripheral frame of the device claimed in the '281 patent operate in the same "way" (by folding and unfolding).

To counter Mullins's testimony about the King device's radial arms, O'Laughlin says two things. O'Laughlin first says that Mullins's opinion about equivalence "read[s] out of the Court's construction the phrase 'carried around the periphery of the member.'" O'Laughlin Rept. at 28. This is true but irrelevant. The question is not whether King's radial umbrella arms are *literally* the same as a peripheral frame (they obviously are not); the question is whether they are *equivalent* to a peripheral frame. On this second point, O'Laughlin simply says, "I do not agree that the umbrella-like radially extending hub-and-spoke 'frames' of the King disclosure are equivalent to a frame carried around the periphery of the member." *Id.* But this is nothing more than an *ipse dixit* — that is, a conclusion supported by no explanation or reasoning. *Cf. Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that a court should not admit opinion evidence that "is connected to existing data only by the *ipse dixit* of the expert.").

A reasonable jury would have to credit Mullins's reasoned opinion over O'Laughlin's *ipse dixit* and would therefore have to conclude that springy radial arms are equivalent to a springy peripheral frame. Thus, a reasonable jury would have to find that the King device meets the "self-expanding structure" means-plus-function limitation of claim 1 of the '281 patent.

With respect to claim 1 of the '281 patent, only one other limitation is in dispute: the limitation requiring that a "substantial portion of the central portion" of the two members be "in

communication with" each other. There is no dispute that when the King device is assembled, the two members (i.e., the two umbrellas) are locked together by a central hub. And the Court finds that by virtue of being locked together at their centers, the two members necessarily communicate movement to each other. This is so self-evident that Mullins simply says that when the hubs are locked together, "the entire central portions (i.e., the hubs) [are] in communication with one another." Mullins Rept. at 28.

To get around the obvious fact that two items that are locked together are "in communication with" each other under the Court's claim construction, O'Laughlin simply ignores the Court's claim construction and substitutes his own. According to O'Laughlin, the locked-together hubs are not in communication with each other because they "do not transmit any *expansion or contraction movement* between each other . . . ." O'Laughlin Rept. at 31 (emphasis added). But the Court's claim construction says nothing about "expansion or contraction movement"; it refers to "movement," plain and simple. Because O'Laughlin's opinion that the two hubs of the King device do not communicate is not based on the Court's claim construction, the Court would not permit him to offer that opinion to the jury.

But O'Laughlin makes a second, less-frivolous argument about the "in communication with" limitation. He says that the umbrellas' hubs are "designed to be as small as possible" and thus the hubs — which are attached to each other — are not "*substantial portions* of the central portions of each umbrella." *Id.* (emphasis added). This argument fails, however, because "in communication with" — as the Court has construed the term — does not mean "attached to."

Whether the umbrellas' hubs, by themselves, are "substantial portions" of the umbrellas' central portions is a close question. *Compare* Mullins Rept. at 28 (describing the hubs as "the

entire central portions" of the umbrellas) *with* O'Laughlin Rept. at 31 (describing the hubs as "small"). But it is not a question that a jury needs to decide, because even if a hub alone does not qualify as a "substantial portion" of an umbrella's central portion, the two umbrellas of the King device still *communicate* by way of the hubs over a much larger area than the hubs alone. Obviously, the movement of one umbrella will be transmitted through the locked-together hubs to the second umbrella. And thus, although a reasonable jury might find that the umbrellas of the King device are *attached* by less than a "substantial portion" of their central portions, a reasonable jury would have to find that the umbrellas *communicate* (through the locked-together hubs) over a substantial portion of their central portions.

In short, as the above discussion shows, a reasonable jury would have to find that the King device anticipates both claim 1 and claim 5 of the '281 patent. Claim 4, however, is a different matter. The Court cannot find that the King device anticipates claim 4.

Claim 4 adds three limitations to claim 1. The first two of these limitations are the mirror image of one another: (1) the "first member in its compressed orientation" must "extend[] primarily distally from the second member," and (2) the "second member in its compressed orientation" must "extend[] primarily proximally from the first member." '281 Pat. col. 18:31-35. The third limitation applies identically to the two members and requires that each member, when expanded, must "extend[] primarily radially outward from its central portion." '281 Pat. col. 18:35-36. It is obvious — and undisputed — that the King device meets the third limitation, because the arms of each opened umbrella of the King device extend radially from each umbrella's hub.

But the Court agrees with the University that the King device does not meet the first two limitations. According to O'Laughlin, the two umbrellas of the King device "extend *towards* each other when compressed" and therefore do not extend distally and proximally from one another as claim 4 requires. O'Laughlin Rept. at 31 (emphasis in original). Implicitly, O'Laughlin is construing the word "extend" as referring to the relationship between the umbrella's tip and its periphery. As the illustrations excerpted above show, when the distal umbrella of the King device is closed, the tip (i.e., the central hub) is located distally from the periphery of the umbrella. Conversely, when the proximal umbrella of the King device is closed, the tip is located proximally from the periphery of the umbrella. In other words, the two umbrellas of the King device are oriented like two ordinary umbrellas placed with their handles touching and their tips at opposite ends. For the King device's umbrellas to extend distally and proximally from each other as O'Laughlin construes the word "extend," however, they would have to be flipped around — that is, they would have to be oriented like two umbrellas with their tips touching and their handles at opposite ends.

In attempting to refute O'Laughlin's opinion that the umbrellas of the King device extend in directions precisely the *opposite* of the claimed directions, Mullins does not explain how he construes the word "extend." Instead, to show that the King device meets claim 4's limitation about proximal and distal extension, Mullins says:

> [I]n its compressed orientation, the first umbrella member of the King [device] is *located* distally of the second umbrella member, just as the first member in the '281 patent. Conversely, in its compressed orientation, the second umbrella member of the King [device] is *located* proximally from the first member, just as the second member in the '281 patent.

Mullins Rept. at 29-30 (emphasis added). As this passage shows, Mullins equates "extending" distally or proximally with "being located" distally or proximally. Mullins does not explain how "being located" and "extending" are equivalent, and the Court finds that, in the context of the '281 patent, they cannot be. The device claimed in the '281 patent has two "members," one for each side of a heart defect to be closed. Of necessity, the members on either side of the defect will be *located* proximally and distally with respect to each other: One member has to be on the far side of the defect, and the other has to be on the near side. Thus, if "being located" and "extending" meant the same thing, two out of the three limitations in dependent claim 4 — the limitations about compressed members *extending* proximally and distally from each other — would be entirely superfluous.

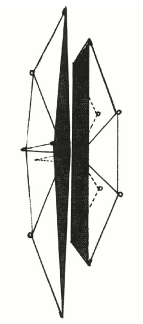
Further, the Court's own analysis of King reveals another reason why a reasonable jury could find that the King device fails to meet claim 4's limitations about proximal and distal extension. Again, claim 4 requires that, when the first member is in its compressed orientation, it must extend primarily distally from the second member. Recall that the two umbrellas in King are delivered one at a time — that is, the second (proximal) umbrella is not delivered until after the first (distal) umbrella is in place. *See* U.S. Pat. No. 3,874,388 col. 9:30 to col. 10:1. This means that, when the first umbrella is in its compressed orientation and being pushed along the catheter, the second umbrella could be anywhere; it could be sitting on an instrument tray, for example. Thus, when the first umbrella is in its compressed orientation (i.e., in the catheter), the first umbrella cannot be said to "extend[] primarily distally" from the second umbrella. For all anyone knows, the two umbrellas could be oriented in the exact same direction, the first inside a catheter and the second on an instrument tray.

In summary, a reasonable jury would have to find that the King device anticipates claims 1 and 5 of the '281 patent, and those claims are therefore invalid. But a reasonable jury would not have to find (and likely would not be *able* to find) that the King device anticipates claim 4.

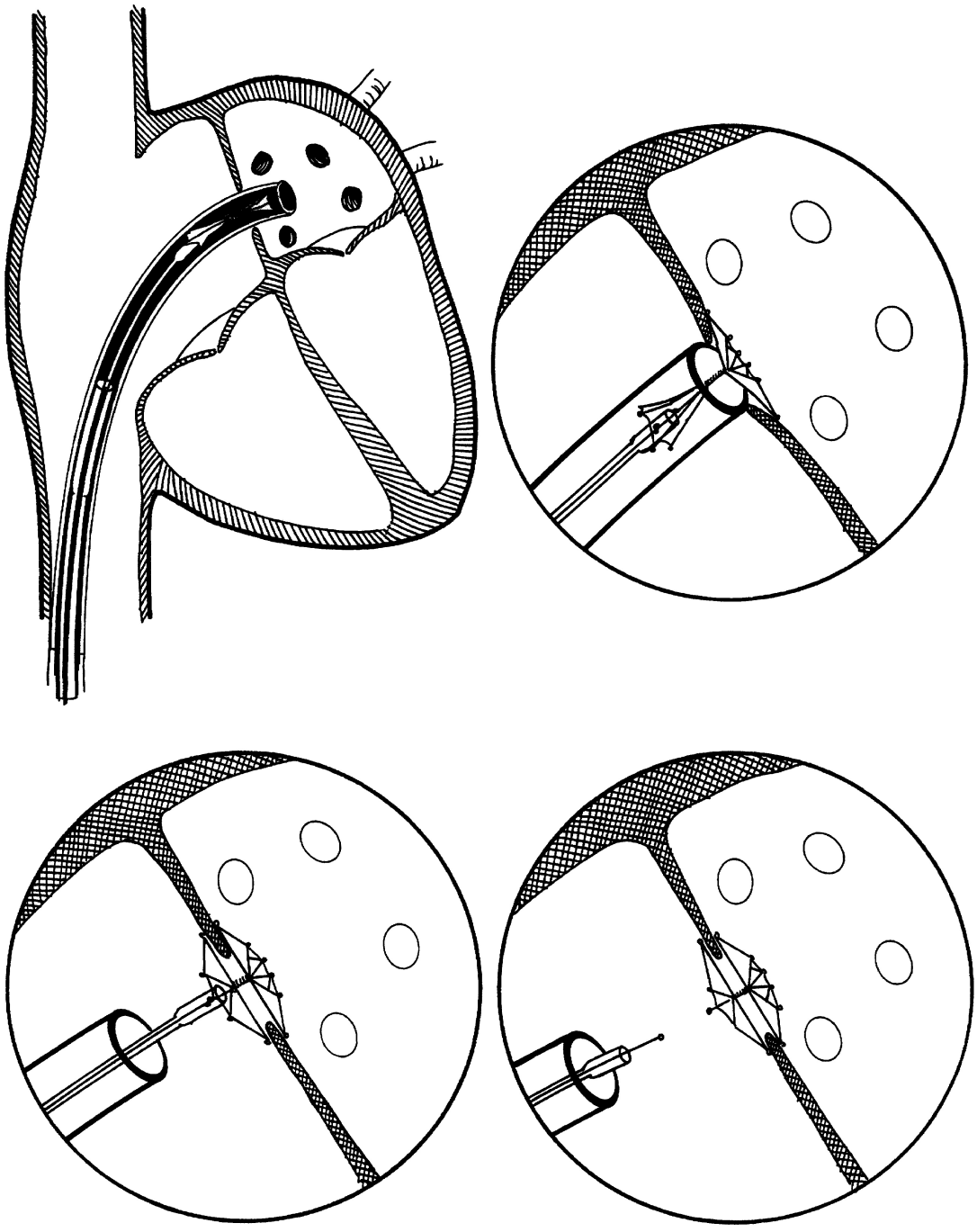
3. The Lock Device

The Lock device, like the King device, is a two-part occluder in which each part is shaped like an umbrella. But the Lock device differs in two important respects from the King device. First, the two parts of the Lock device are attached before delivery and are thus delivered at the same time. Second, the two parts of the Lock device are oriented in the opposite direction from the two parts of the King device. That is, in the Lock device, the two umbrella-shaped parts are oriented like umbrellas joined at their tips, not at their handles.

The following drawing from the Lock article depicts the Lock device in its expanded position:



Lock article at 1095 Fig. 5. And the following four drawings show, step-by-step, how the Lock device is delivered and deployed:



Lock article at 1096 Fig. 6.

It is apparent — and the University does not dispute — that the Lock device pictured in these illustrations meets the following limitations of the asserted claims of the '281 patent: the Lock device has first and second "members" (the umbrellas); the members have a "compressed orientation" that fits within a catheter and an "expanded orientation having an enlarged diameter"; the umbrellas include a "flexible fabric disk" (as called for by claim 5); a portion of the opened umbrellas is held "tautly" against the septum; the members extend distally and proximally from each other in their compressed orientation (as called for by claim 4); and the members extend radially in their expanded orientation (also as called for by claim 4). *See* O'Laughlin Rept. at 36-39 (opining that Lock device does not anticipate and not discussing any of these limitations).

But the University — again relying on O'Laughlin — denies that the Lock device meets two other limitations. First, O'Laughlin says that the Lock device (like the King device) lacks "a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation . . . and an expanded orientation." *See* O'Laughlin Rept. at 36. Second, O'Laughlin says that the Lock device (like the King device) lacks substantial portions of central members "in communication with" each other. *See id.* at 38-39.

As noted above, the first of these two limitations, as construed by the Court, requires one of two structures: either "(1) a flexible, elastically deformable frame carried around the periphery of the member; or (2) a frameless membrane made of a thin piece of a superelastic material." *Markman* Order at 21.

O'Laughlin asserts — correctly — that the Lock device does not include either type of structure. O'Laughlin Rept. at 36. And Mullins, on AGA's behalf, agrees. But Mullins asserts that the springy[10] radial umbrella-type frame of the Lock device is *equivalent to* a peripheral frame. *See* Mullins Rept. at 41 ("[T]he umbrella frame structure of Lock is an equivalent structure to the peripheral leg frames disclosed in the '281 patent for the purpose of the stated function."). And Mullins supports this assertion with an analysis of how, specifically, the Lock umbrella-type frame literally performs the claimed function and also satisfies the "way-result" test, *see Odetics*, 185 F.3d at 1267, for determining whether two structures are equivalent for purposes of a means-plus-function limitation.[11]

O'Laughlin responds in the same inadequate way he responded when the issue of equivalence was raised in connection with the King device. O'Laughlin protests that treating the umbrella-type frame as equivalent to a peripheral frame "read[s] out of the Court's construction the phrase 'carried around the periphery of the member,'"O'Laughlin Rept. at 36 — a non sequitur. And on the question of equivalence, O'Laughlin — as he did with respect to the King

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[10]The radial arms of the Lock device are described as springy. *See* Lock et al., *Transcatheter Closure of Arterial Septal Defects: Experimental Studies*, 79 Circulation 1091, 1097 (1989) ("A new double-umbrella device was designed to allow the arms to fold back against each other, thus using spring tension rather than hooks to fix the device on the septum.").

[11]Mullins Rept. at 41-42 ("[T]he legs between the resilient loops of the '281 patent operate in the same *way* as the arms in Lock because they are folded to allow the frame to be made small enough to fit within the catheter and they then unfold upon exiting the catheter to permit the frame member to assume an expanded orientation with an enlarged diameter. The *result* achieved by the legs in the '281 patent and the arms in Lock is the same. They fold to allow the frame member to be inserted into a catheter for passage and then they unfold automatically allowing the frame to return to an expanded orientation with an enlarged diameter. . . . The differences between the leg arrangements of the '281 patent and the arm arrangements of Lock are minor and insubstantial." (emphasis added)).

device — fails to offer any evidence or analysis of the way-result test or of whether the claimed function is literally met. Instead, O'Laughlin simply offers an *ipse dixit*: "I do not agree that the radially extending hub-and-spoke 'frames' of the Lock disclosure are equivalent to a frame carried around the periphery of the member." *Id.* at 36. Because a reasonable jury would have to credit Mullins's reasoned testimony over O'Laughlin's naked say-so, a reasonable jury would have to find that the Lock device's umbrella-type frame meets the limitation of the '281 patent calling for "a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation . . . and an expanded orientation."

O'Laughlin challenges only one other limitation: the limitation calling for "a substantial portion" of the two members being "in communication with" each other. O'Laughlin has two theories for why this limitation is not met by the Lock device. First, he says that the two umbrellas of the Lock device do not communicate because "there is no transmission of any expansion or contraction movement between the central portions of the members . . . ." O'Laughlin Rept. at 38. This argument fails for the reasons already given in the Court's discussion of the King device: The Court's claim construction calls for the transmission of "movement," not "expansion or contraction movement."

Second, O'Laughlin says — as he did with respect to King — that the point of contact between the two umbrellas of the Lock device is too small to be a "substantial portion" of the umbrellas' central portion. *Id.* This argument likewise fails for the reasons given above in the Court's discussion of the King device: The two "members" do not have to be *attached* by a "substantial portion" of their central portions; they need only *communicate* — here, transmit movement — between a substantial portion of their central portions. It is obvious that

movement of one umbrella will be transmitted to the other umbrella by means of their central attachment point. Thus, although a reasonable jury might find that the umbrellas of the Lock device are *attached* by less than a "substantial portion" of their central portions, a reasonable jury would have to find that the umbrellas *communicate* (by way of their central attachment point) over a substantial portion of their central portions.

In short, a reasonable jury would have to find that the Lock device anticipates claims 1, 4, and 5 of the '281 patent.

C. Enablement

Under the first paragraph of 35 U.S.C. § 112, a patentee must describe his invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use" the invention. 35 U.S.C. § 112, ¶ 1. This is commonly known as the "enablement" requirement. *See, e.g.*, *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1238 (Fed. Cir. 2003). To satisfy the enablement requirement with respect to a particular claim, the patentee must, in the patent's specification, enable the full scope of the claim; otherwise, the claim is invalid. *See id.* at 1241.

In this case, under the applicable scheduling order (as amended), ordinary fact discovery closed on September 29, 2009, and expert discovery closed on March 8, 2010. *See* Order Am. Pretrial Order Oct. 8, 2009 [Docket No. 160], Order Am. Pretrial Order Feb. 19, 2010 [Docket No. 190]. The University contends — and AGA does not deny — that throughout this entire discovery period, AGA never raised a lack-of-enablement defense, and AGA's experts never opined (except in passing) that any claim of the '281 patent was invalid for lack of enablement. *See* Pl. Mem. Opp. SJ re Validity at 10 [Docket No. 258].

The same day that fact discovery closed — and while expert discovery was ongoing — the Court issued its *Markman* order construing the disputed claim language. Then in January 2011, the Court issued a summary-judgment order. In that order, the Court — after having received supplemental briefing from the parties — abandoned its earlier construction of the term "in communication with" in favor of a new construction. The Court refused to construe one term ("member"). *Id.* at 15-17. And the Court modified the form — but reaffirmed the substance — of its earlier constructions of the term "tautly holding," *id.* at 12-15, and of the group of terms "affixed," "joined," and "connected," *id.* at 3-5.

In light of the Court's revised construction of the term "in communication with," the parties understandably wanted to engage in additional expert discovery. And had they sought permission to engage in such discovery, the Court would have readily granted it. But the parties did not move for an extension of the discovery schedule, as Local Rule 16.3 requires. *See* D. Minn. LR 16.3(a) ("Once the pretrial discovery schedule is adopted, it shall not be extended or modified *except upon written motion* and for good cause shown." (emphasis added)). Instead, they reached a private agreement about the timing of supplemental expert discovery, and they agreed "not to burden the Court with a formal stipulation and proposed order concerning" their agreed-upon schedule. Axtell Decl. [Docket No. 250] Ex. J at 2.

Although the Court generally applauds parties who work together to resolve scheduling and discovery-related disputes, parties cannot, by agreement, suspend the local rules. The parties are not the only ones affected by a scheduling order; the Court has an independent interest in seeing that its scheduling orders are followed. Moreover, the parties' failure to comply with LR 16.3 in this case has created a dispute that would not have arisen had they complied with the

rule. Specifically, the Court, in modifying the scheduling order to accommodate supplemental expert discovery, would have narrowly limited such discovery to topics related to the Court's revised construction of "in communication with." Because AGA's enablement arguments have nothing to do with this claim term, the Court would not have permitted AGA to supplement its expert reports on the issue of enablement.

But AGA *did* supplement its expert reports on the issue of enablement. According to AGA, such supplementation is permissible for two reasons. First, AGA says that the University stipulated to additional expert discovery on the topic of enablement. Def. Mem. Opp. Pl. Mot. Exclude at 3-6 [Docket No. 251]. Second, AGA says that its untimely expert opinions on enablement are admissible because AGA's failure to disclose those opinions before the expert-discovery deadline in the operative scheduling order (i.e., by March 8, 2010) "was substantially justified or is harmless" under Fed. R. Civ. P. 37(c)(1). Def. Mem. Opp. Pl. Mot. Exclude at 6-19. The Court rejects both arguments.

To begin with, the University did not stipulate to additional discovery on the topic of enablement, as AGA asserts. In initiating negotiations about supplemental expert discovery, AGA told the University in an email:

> AGA intends to move for summary judgment of invalidity under 35 U.S.C. §§ 102 and 103 on the basis of the Court's substantially revised construction of "in communication with." AGA also intends to move under [35 U.S.C.] § 112 on the basis that there is *no written description* of the invention as construed by the Court. Accordingly, it makes sense for the parties to agree to supplement their respective expert reports *to take into account the Court's new construction* and adequately prepare their contentions and defenses.

Axtell Decl. Ex. J at 6 (emphasis added). There is no evidence that the parties clarified the subject of the supplemental expert discovery any further.

The University's eventual agreement that supplemental expert discovery was appropriate did not in any way amount to an agreement that enablement was a legitimate topic of that supplemental discovery. For one thing, "written description" and "enablement" are distinct requirements under the first paragraph of 35 U.S.C. § 112. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc). Perhaps AGA used the term "written description" carelessly in its email and in fact meant "enablement"; if so, AGA must live with the consequences of its carelessness. AGA cannot plausibly claim that the University acceded to a request to allow discovery on enablement when AGA referred in its email only to the written-description requirement.

Further, although AGA announced in its email a basis for its planned summary-judgment motion (namely, the written-description requirement), AGA did not clearly link that basis to the proposed supplemental discovery. In the first sentence quoted above, AGA indicated that the Court's "substantially revised construction of 'in communication with'" would underpin AGA's arguments for invalidity based on obviousness (under § 103) and anticipation (under § 102). But AGA said that its written-description argument would be based on "the invention as construed by the Court." AGA did *not* say that the argument would be based on the Court's new construction of "in communication with." Thus, when AGA proposed supplemental discovery "to take into account the Court's *new construction*," it appeared that the only "new construction" that AGA was referring to was the construction of "in communication with." How could it be otherwise? There was only one new construction in the Court's order, just as there was only one new

construction referred to in AGA's email: the construction of "in communication with." The University agreed to supplemental expert discovery related to that new construction, not to supplemental discovery on an enablement argument that had nothing to do with that new construction.

Finally, AGA's untimely disclosure of its expert opinions related to enablement was neither substantially justified nor harmless. AGA's enablement argument is simple: According to AGA, the '281 patent is invalid because it does not enable a frameless embodiment of the invention. According to AGA, it did not do any discovery on this argument until after the Court's summary-judgment order because AGA did not know, until that order, that the Court construed the claims to cover a frameless embodiment. Def. Mem. Opp. Pl. Mot. Exclude at 2 ("It was not until the Court *revised* its claim construction in January of 2011 that it became clear that the Court's construction of claim 1 did not require a frame." (emphasis in original)).

AGA's argument is frivolous. In its opening *Markman* brief, AGA argued that a frame was required by the phrase "a self-expanding structure exhibiting a spring-like behavioural component" in claim 1 of the '281 patent. *See* Def. Opening *Markman* Br. at 28-37 [Docket No. 65]. In construing this phrase, the Court expressly rejected AGA's argument. The Court construed the phrase as a means-plus-function limitation and said that the patent "link[ed] a *frameless*, superelastic membrane to the claimed function" of the limitation. *Markman* Order at 25 (emphasis added).

Rather than accepting the obvious import of the Court's *Markman* order — namely, that the '281 patent covered a frameless device — AGA decided to play games. The Court, in construing the term "tautly holding" in its *Markman* order, had used the phrase "like a drum

head" simply to illustrate what "taut" meant. *Markman* Order at 16. AGA decided to try to play "gotcha" with this construction. Although the Court had plainly rejected AGA's only overt attempt to smuggle a frame into its proposed claim construction, AGA decided to act — throughout the entire period between the Court's *Markman* order and the Court's summary-judgment order — as if the Court had *itself* smuggled a frame into the limitation "tautly holding," simply by using the example of a drum head in defining "taut."

AGA now argues that after the Court's *Markman* order, "AGA in good faith believed based on the Court's construction of *other* limitations in claim 1 that the claims nonetheless required a frame." Def. Mem. Opp. Pl. Mot. Exclude at 2 (emphasis in original). Any such belief on AGA's part may have been in good faith (although the Court has its doubts), but it certainly was not reasonable. As the Court said in its summary-judgment order, "*[n]o reasonable reader* of the Court's *Markman* order could believe that the Court, by using the words 'taut, like a drum head,' intended to construe the patents-in-suit as calling for a frame that pulls the surface of an occluding disk tight." Second SJ Order at 15 (emphasis added).

In short, after the Court's *Markman* order, AGA had a choice: read the Court's claim construction reasonably, or distort that construction to serve AGA's strategic purposes. Had AGA read the Court's construction reasonably, AGA could have done expert discovery during the ordinary expert-discovery period on its argument that a frameless embodiment is not enabled. Instead, AGA clung to an unreasonable, strategically motivated reading of the Court's *Markman* order throughout the discovery period. The Court's rejection of that unreasonable reading in the Court's summary-judgment order does not justify AGA in offering new, untimely expert

opinions on the issue of enablement. *Cf. In re Perry*, 918 F.2d 931, 934 (Fed. Cir. 1990) ("[An] 'empty head and pure heart' defense will not excuse objectively unreasonable conduct.").

Further, the untimeliness of AGA's expert opinions on enablement is not "harmless" under Fed. R. Civ. P. 37(c)(1). Under the parties' privately negotiated extension of expert discovery, the University had 30 days to prepare a rebuttal expert report addressing AGA's new expert opinions about enablement. Given the late stage of the case and the fact that AGA did not previously indicate that it was raising an enablement defense, the Court finds it both unreasonable and unfair to expect the University to respond to AGA's enablement arguments in such a short period of time.

Moreover, AGA's untimely arguments and evidence about enablement have already created additional delay in these already lengthy proceedings because the Court has had to entertain briefing and argument on both the substance of the enablement argument and the procedural issue of whether to exclude AGA's enablement-related evidence. Had AGA done expert discovery on the argument in a timely fashion, the University's procedural defense would not have arisen. Likewise, had AGA and the University complied with Local Rule 16.3, this controversy would not have arisen because the Court would not have permitted AGA to do additional discovery on its enablement defense. The Court will not allow AGA to use evidence that exists only because AGA — with the University's partial consent, but nevertheless in violation of a local rule — engaged in some discovery that it had no right to engage in under the governing scheduling order.

Because AGA's failure to timely disclose its experts' opinions about enablement is not harmless and is certainly not substantially justified, the Court excludes those opinions. The

Court recognizes that without those opinions, AGA cannot raise an enablement defense. But under the circumstances, AGA's need to raise that defense, and the related public interest in determining whether the '281 patent is invalid for lack of enablement, cannot outweigh the importance of moving this case forward in an orderly fashion and in accordance with the Federal Rules of Civil Procedure, the Court's local rules, and the governing scheduling order. *See Wegener v. Johnson*, 527 F.3d 687, 692 (8th Cir. 2008) ("When fashioning a remedy [for an untimely disclosure], the district court should consider, *inter alia*, the reason for noncompliance, the surprise and prejudice to the opposing party, the extent to which allowing the information or testimony would disrupt the order and efficiency of the trial, and the importance of the information or testimony.").

D. Indefiniteness

Under the second paragraph of 35 U.S.C. § 112, a patent must, in its claims, "particularly point[] out and distinctly claim[] subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. It follows that a patent claim must be sufficiently definite so that "one skilled in the art would understand the bounds of the claim when read in light of the specification . . . ." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). A claim that fails to satisfy this definiteness requirement is invalid as indefinite.

If a claim is "amenable to construction, however difficult that task may be," then the claim is not invalid as indefinite. *Id.* Put another way, "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over

which reasonable persons will disagree," then the claim is not invalid as indefinite. *Id.* Conversely, "[i]f a claim is insolubly ambiguous, and no narrowing construction can properly be adopted," then the claim is invalid as indefinite. *Id.*

According to AGA, the following language in claim 1 is insolubly ambiguous, rendering the claim invalid as indefinite:

> a self-expanding structure
>
> > exhibiting a spring-like behavioural component for moving the member between a compressed orientation for passage through a medical instrument having an inner diameter and an expanded orientation having an enlarged diameter
> >
> > for tautly holding at least a portion of the closure device against a septum . . .

'281 Pat. col. 18:12-18 (line breaks added for clarity). The Court agrees with AGA.

As the Court noted in its *Markman* order, the syntax of this phrase is so confused that the phrase is utterly unparseable. *Markman* Order at 19. The prepositional phrase "for tautly holding" modifies something — but what? There are at least four — and perhaps even five — possibilities. First, the quoted claim language might call for a "self-expanding structure . . . for tautly holding." Second, the claim language might call for a "spring-like behavioural component . . . for tautly holding." Third, the claim language might call for an "expanded orientation . . . for tautly holding." Fourth, the claim language might call for an "enlarged diameter for tautly holding." Finally, the words "for tautly holding" might be intended to modify something whose existence is implied but which is not captured by any single noun or noun phrase that "for tautly holding" could modify — namely, the "springing" process or action that the "self-expanding structure" goes through when it is pushed out of a "medical instrument."

At the *Markman* stage, the Court did not have to decide what "for tautly holding" modified. At that stage, the parties' dispute was really about the meaning of "taut," and the Court was able to resolve that dispute by construing "tautly holding" in isolation.[12]

But AGA has now squarely raised the issue of whether the claim language including the phrase "for tautly holding" can be construed or is, in fact, insolubly ambiguous. In arguing that this claim language is not indefinite, the University relies largely on the Court's earlier statement that "the *gist* of claim 1 of the '281 Patent, and of the 'tautly holding' claim language, is clear enough." *Markman* Order at 19 (emphasis in original); Pl. Mem. Opp. SJ re Validity at 28-29.

The Court continues to believe that the claim language is clear enough to construe the phrase "tautly holding" in isolation — which is all that the Court did in its *Markman* order. But construing "tautly holding" is not the same thing as construing "*for* tautly holding." To construe "*for* tautly holding," the Court must identify what the phrase modifies, and that is an impossible task. Needless to say, if the Court cannot identify the thing that is "for tautly holding" a portion of a closure device in place, neither can a potential infringer. The claim therefore does not "particularly point[] out and distinctly claim[]" what it covers as required by paragraph two of § 112. For that reason, the Court holds that claim 1 of the '281 patent is invalid as indefinite.

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[12]In its *Markman* order, the Court held as follows:

> The term "tautly holding" derives from the phrase "to hold tautly." "To hold something tautly against a septum" means both (1) to hold that thing itself taut, like a drum head, and (2) to hold that thing tightly against a septum.

Markman Order at 16. The Court subsequently amended this construction by adding the phrase "or the surface of an inflated balloon" after "like a drum head." Second SJ Order at 12-13.

Because the remaining claims in the '281 patent are dependent on claim 1, they are likewise invalid as indefinite.

E. Counterclaims

Because the Court earlier held that AGA does not infringe the '291 patent — and because the Court now holds that the '281 patent is invalid — the University cannot recover against AGA on any of its claims. Typically, this would lead to a dismissal of the University's complaint and the entry of final judgment in AGA's favor. In this case, however, AGA has filed various counterclaims alleging that the patents-in-suit are invalid, are not infringed, and are unenforceable, and the Court has not ruled on some of those counterclaims. Under the circumstances, the Court finds that judicial efficiency and the interests of justice warrant dismissing AGA's pending counterclaims as moot. *See, e.g., Phonometrics, Inc. v. N. Telecom Inc.*, 133 F.3d 1459, 1468 (Fed. Cir. 1998) ("[A] district court has discretion to dismiss a counterclaim alleging that a patent is invalid as moot where it finds no infringement.").

A ruling on AGA's noninfringement counterclaim with respect to the '281 patent cannot benefit the public, since a ruling on that counterclaim would be limited to devices made by AGA. And such a ruling would be of limited benefit to AGA given that the Court has found the '281 patent invalid. In contrast, a decision finding the '291 patent invalid *would* benefit the public (and not just AGA). But there is no guarantee that the Court (or a jury) would find the '291 patent invalid. And if the Court (or a jury) did not find that the '291 patent was invalid, little would be gained, as other accused infringers could still challenge the validity of the '291 patent in future proceedings.

In short, the limited potential value of adjudicating AGA's pending counterclaims does not support expending scarce resources litigating those issues in this Court. This District is one of the busiest in the United States, and this Court has already devoted an enormous amount of time to this case. AGA has won, the University has lost, and the Court is not going to devote more time to litigating issues that are unlikely to be of consequence to anyone. The Court therefore dismisses AGA's remaining counterclaims as moot and directs the entry of judgment.

ORDER

Based on the foregoing and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Plaintiff Regents of the University of Minnesota's motion [Docket No. 247] to exclude new expert opinions of Professor Ken Gall and Dr. Charles Mullins is GRANTED as follows:
   a. In Gall's substitute expert report, all portions related to his opinion that the '281 patent is not enabled are EXCLUDED.
   b. In Mullins's substitute expert report, all portions related to his opinion that the '281 patent is not enabled are EXCLUDED:
2. Defendant AGA Medical Corporation's motion for summary judgment of invalidity [Docket No. 240] is GRANTED IN PART as follows:
   a. Count 2 of plaintiff Regents of the University of Minnesota's first amended complaint [Docket No. 79] for infringement of U.S. Patent No. 6,077,281 is DISMISSED WITH PREJUDICE AND ON THE MERITS.

b. The Court DECLARES, as requested in Counterclaim 2 of defendant AGA Medical Corporation's first amended answer and counterclaims [Docket No. 229], that claims 1, 4, and 5 of U.S. Patent No. 6,077,281 are INVALID as anticipated and as indefinite.

3. Defendant AGA Medical Corporation's motion for summary judgment of invalidity [Docket No. 240] is DENIED in all other respects.

4. Defendant AGA Medical Corporation's remaining counterclaims are DISMISSED AS MOOT.

5. In light of the Court's dismissal in its earlier order [Docket No. 231] of Count 1 of the first amended complaint for infringement of U.S. Patent No. 6,077,291, and the Court's dismissal in this order of Count 2 of the first amended complaint for infringement of U.S. Patent No. 6,077,281, plaintiff Regents of the University of Minnesota's first amended complaint is DISMISSED WITH PREJUDICE AND ON THE MERITS.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: December 14, 2011

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge